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09/284,421	06/11/1999	JOHN FRANCIS GORDON	043601/0110	2286

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BEX, PATRICIA K

ART UNIT	PAPER NUMBER
1743	21

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/284,421	GORDON, JOHN FRANCIS
	Examiner P. Kathryn Bex	Art Unit 1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 08 August 2002.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 45-155 is/are pending in the application.

4a) Of the above claim(s) 45-88, 100-104 and 132-155 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 89-99 and 105-131 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on 08 August 2002 is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All . b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____

Art Unit: 1743

## DETAILED ACTION

1. Any rejection and/or objection not repeated herein has been withdrawn.

### *Drawings*

2. New Figure 8 received on August 06, 2002 is acceptable.

### *Claim Objections*

3. Claim 99 objected to because of the following informalities: Examiner recommends that "an" be removed from the claim for clarity. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 89, 93, 96, 105-109, 112, 123-124 are rejected under 35 U.S.C. 102(e) as being anticipated by Croteau *et al* (USP 5,700,655).

Croteau *et al* teach a multi-well assay disc plate 10 comprising; a lid, a second lower surface having a plurality of wells 12 disposed therein, the lid and second surface defining a chamber having an opening 24 which allows fluids to be introduced and withdrawn from the chamber. The plate is made from a hydrophobic material. Moreover, each well is adapted to hold an aliquot of liquid and is sized and shaped and formed of a suitable material to hold the

Art Unit: 1743

aliquot with the well by surface tension. Additionally, the surface of the wells can be treated with a hydrophilic material to enhance the retention of the liquid in the wells (column 2, lines 43-45, column 4, line 52- column 6, line 60, Figs. 2A-4B).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 90-92, 94-95, 111, 113-115, 125, 127-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Zanzucchi *et al* (USP 5,585,069).

Croteau *et al* as discussed previously, do not teach a plate structure which is divided into sectors such that the space between the upper and lower plates is subdivided to provide a plurality of spaces, each space provided with a fluid introduction opening and vent opening to enable independent access to each space. However, such a design is considered conventional in

the art, see Zanzucchi *et al.* Zanzucchi *et al* do teach a disc structure 14 which is divided into modular sectors 48 comprising a loading channel 34 and wells 36, 40, 42, 44, vent 46 and a second opening 50 at the peripheral edge of the plate. Additionally, Zanzucchi *et al* teach a loading system 30 which may house one or more capillary tubes 32. As the sample loading tube is inserted into the loading channel of a disc sector, a sealant which can be adhered to the edge of the capillary sample tube or the loading channel, seals the capillary tube to the channel (column 5, line 65- column 6, line 2, Figs. 1A-3). Such use of a plurality of modules allows a large number of tests to be performed in parallel (column 4, line 60-62).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the assay apparatus of Croteau *et al* the handle means, as taught by Zanzucchi *et al*, in order perform a large number of independent tests in parallel.

Croteau *et al* discloses the claimed invention except for the spacing between the upper and lower plates less than 1.0 or 0.5 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the spacing between the upper and lower plates less than 1.0 or 0.5 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

9. Claims 90-92, 98-99, 110-120, 125-129, 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Merkh *et al* (USP 5,281,540).

Croteau *et al* as discussed previously, do not teach a disc structure which is divided into removable sectors. The disc structure including digitally encoded address information provided for optical inspection. Merkh *et al* do teach a disc structure 18 which is divided into sector

Art Unit: 1743

inserts 80 comprising wells 84. The system of Merkh *et al* includes a liquid injecting device 31 which penetrates the self-sealing cover 90 of each sector at port 92 (column 10, lines 1-7). Merkh *et al* teach the sector insert having digitally encoded address information 94 for use with a device having an optical inspection means 316 (column 30, line 51- column 32, line 54, Figs.1-2, 4-5, 14). Moreover, Merkh *et al* teach sectors inserts and a disc which include lock 100, 102, 104 and key 93 portions to allow the sectors to be snap-fitted in the correct orientation and the disc comprising plurality of dividing walls 122.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the assay apparatus of Croteau *et al* the digitally encoded address information means, as taught by Merkh *et al*, in order allow the operator to easily access patient information corresponding to the particular assay sector (column 10, line 60- column 11, line 21).

Croteau *et al* discloses the claimed invention except for the spacing between the upper and lower plates less than 1.0 or 0.5 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the spacing between the upper and lower plates less than 1.0 or 0.5 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. Claims 97, 116 and 130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Takase *et al* (EP 417 305 A1).

Croteau *et al* as discussed previously, do not teach wherein either of the upper or lower plates includes a reflecting surface. Takase *et al* teach a liquid sample analyzer. The analyzer

Art Unit: 1743

comprising a disc 101 with wells 104 and liquid sample supply means 9 for supplying liquid sample to the wells. Additionally, the analyzer system comprises a measuring means for measuring the reaction product produced. The disc has information formats 101, i.e. digitally encoded information, needed for analysis. The formats can be processed via a reflection method in which a reflecting film 101b can be formed on the upper or lower plates. A reading head 19 is arranged above and/or below the formats to provide the predetermined information (page 11-12, Fig. 8b).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included the within the disc of Croteau *et al*, with the reflective surface in order to provide a reliable and permanent means of storing information pertaining to the reaction disc.

11. Claims 121-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Ford (USP 4,722,598).

Croteau *et al* as discussed above, do not teach an assay plate including one or more lenses molded into the structure to improve the optical inspection of the surface locations. Ford does disclose a base and cover plate. The base plate includes shallow wells 4 for holding a biological sample. The base plate includes thin transparent bottom lens 7 that is integrally formed and which define the bottom of each sample well (column 3, lines 1-68, Figs. 1-8). Such use of a bottom lens avoids any optical distortion which might occur during microscopic observation of the sample contained in the various sample wells (column 3, lines 60-68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included the within the assay plate of Croteau *et al*, the integrally

Art Unit: 1743

molded lens, in order to avoid any optical distortion which might occur during microscopic observation of the sample contained in the various sample wells.

*Response to Arguments*

12. Applicant's arguments filed August 6, 2002 have been fully considered but they are not persuasive. In response to the previous rejection of claims 89, 93, 96, 105-109, 112, 123-124 under 35 U.S.C. 102(e) as being anticipated by Croteau *et al* (USP 5,700,655), Applicant argues that excess liquid can be removed through the pour spout 24 when the lid slit is aligned with pour spout 24, but there is no suggestion of adding liquids when the lid is in place. Examiner contends that method limitations, e.g. introduction or removal of liquids, are not accorded patentable weight in a claim drawn to an apparatus. Moreover, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. (Emphasis added.) If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Examiner maintains that the pour spout and slit of the lid is fully capable of allowing the introduction of fluids into the chamber when in alignment.

In response to the rejection of claims 90-92, 94-95, 111, 113-115, 117, 125, 127-128 under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Zanzucchi *et al* (USP 5,585,069), Applicant argues that Zanzucchi *et al* do not teach a second opening at the peripheral edge of the plate. Examiner points out that Zanzucchi *et al* do teach a second opening 50 at the peripheral edge of the plate (column 4, lines 55-58). Moreover, Applicant argues that Zanzucchi *et al* do not teach a structure subdivided by one or more

Art Unit: 1743

dividing walls to provide a plurality of spaces, each spacing being provided with an inlet and vent opening to enable each space to be independently filled. Examiner does not agree since Zanzucchi *et al* do teach "modular" radial slices which are each provided on the disc with divisions 48 that make up the modules (Figs. 1B-2). Wherein each module has an inlet 34 and vent 46 (column 4, line 60-62, column 6, lines 32-50).

In response to the rejection of claims 90-92 under 35 U.S.C. 103(a) as being unpatentable over Croteau *et al* (USP 5,700,655) in view of Merkh *et al* (USP 5,281,540), Applicant argues that Merkh *et al* is not related to a disc structure which is divided into removable sectors. Examiner points out that claims 90-92 or claim 89 do not disclose any removable sectors.

***Conclusion***

13. No claims allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Art Unit: 1743

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

*Kathryn Bex*

P. Kathryn Bex

Patent Examiner

AU 1743

October 21, 2002

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